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K003404
Page 1 of 2

8.0 510(k) Summary

510(k) Summary
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

The Product
- SupraSperm System (Cat. No. 1091 and 1092)

Indications for use:
SupraSperm System is intended to be used for the separation and purification of spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART).

The product formulation:
NidaCol (HEPES buffered salt solution with silane-coated silica colloid)
Sperm Preparation Medium (K 991332) containing:
EBBS (Earle's Balanced Salt Solution)
Sodium pyruvate
Human Serum Albumin
Assisted Reproduction Technology Supplement (ARTS)
HEPES
Sodium Bicarbonate
Streptomycin
Penicillin
Phenol Red

Product Testing Control Contents:
Sterility test
pH
Osmolality
Endotoxin: ≤ 1.0 EU / ml (LAL-test)
Sperm Survival Test

Note: The results for each batch are stated on a Certificate of Analysis, which is available upon request.

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Assisted Reproduction Technology Supplement (ARTS)
HEPES
Sodium Bicarbonate
Streptomycin
Penicillin
Phenol Red

Product Testing Control Contents:
Sterility test
pH
Osmolality
Endotoxin: ≤ 0.10 EU / ml (LAL-test)
Sperm Survival Test

Note: The results for each batch are stated on a Certificate of Analysis, which is available upon request.

Stability and Biocompatibility Testing

The data obtained in the present stability study indicate that SupraSperm System was stable up to 15 weeks after production and non toxic according to sperm survival test.

Clinical Documentation:

SupraSperm System has been compared to PureSperm (K984172) from NidaCon Intenational AB in a parallel study at the University Hospital of Copenhagen. There is no significant difference in the results with regard to the total number of sperm cells, motile sperm and progressive motile sperm cells. (Ziebe, Medi Cult Internal Report)

SupraSperm was marketed in Europe in September 1999. There have been no registered complaints on the product and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Therefore, based on the clinical data presented we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products is substantially equivalent to the predicated device PureSperm from NidaCon International AB.

Prepared and Submitted by:

Ronald G. Leonardi

October 31, 2000

Ronald G. Leonardi, Ph.D.
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
858-586-0751

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Medi-Cult a/s
c/o Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K003404
SupraSperm System
Dated: December 26, 2000
Received: December 28, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Leonardi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K003404

510(k) Number (if known)

Device Name: Medi-Cult SupraSperm System

Indications for Use:

SupraSperm System is intended to be used for the separation and purification of spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART).

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003404